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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/901,782	07/09/2001	Susan Hardin	IVGN1013	9388

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TROUTMAN SANDERS LLP  
5200 BANK OF AMERICA PLAZA  
600 PEACHTREE STREET, N.E.  
SUITE 5200  
ATLANTA, GA 30308-2216

EXAMINER
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SISSON, BRADLEY L

ART UNIT	PAPER NUMBER
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1634

NOTIFICATION DATE	DELIVERY MODE
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09/02/2011

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

jim.schutz@troutmansanders.com  
patents@troutmansanders.com  
ryan.schneider@troutmansanders.com

<b>Office Action Summary</b>	<b>Application No.</b> 09/901,782	<b>Applicant(s)</b> HARDIN ET AL.	
	<b>Examiner</b> Bradley L. Sisson	<b>Art Unit</b> 1634	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 11 July 2011.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on \_\_\_\_; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 5) ☒ Claim(s) See Continuation Sheet is/are pending in the application.
- 5a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 6) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 7) ☒ Claim(s) See Continuation Sheet is/are rejected.
- 8) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 9) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 10) ☒ The specification is objected to by the Examiner.
- 11) ☒ The drawing(s) filed on 10 September 2010 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 12) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. ____.                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>11 July 2011</u> .  | 6) <input type="checkbox"/> Other: ____.                          |

Continuation of Disposition of Claims: Claims pending in the application are 10,16-18,50,51,53-55,64-69,71,72,74,76,77,79-82,84-87,89-92,95-98,100,102-106 and 108-111.

Continuation of Disposition of Claims: Claims rejected are 10,16-18,50,51,53-55,64-69,71,72,74,76,77,79-82,84-87,89-92,95-98,100,102-106 and 108-111.

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114 was filed in this application after appeal to the Board of Patent Appeals and Interferences, but prior to a decision on the appeal. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 11 July 2011 has been entered.

### ***Information Disclosure Statement***

2. Acknowledgement is made of applicant filing an Information Disclosure Statement in triplicate on 11 July 2011. While the cited documents have been considered, duplicate listings of the documents have been lined through.

### ***Drawings***

3. The drawings were received on 10 September 2010. These drawings are acceptable.

### ***Specification***

4. The abstract of the disclosure is objected to because it does not refer to the claimed subject matter. Correction is required. See MPEP § 608.01(b).

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***Claim Rejections - 35 USC § 112***

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 17, 54, 68, 76, 79, 80, 85, 86, 87, 90, 91, 96, 97, 105, 106 and 108-111 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

7. Claims 17, 54, 68, 76, and 97 are indefinite as a result of the use of the term "comprises." As presently worded, one of skill in the art would not be able to readily determine the metes and bounds of the "fluorescent property." Similarly, claims 85-87 are indefinite as a result to the use of the term "comprises" as it is not readily apparent what constitutes the metes and bounds of the recited groups.

8. The term "about" in claim s 79, 80, 81, 90, 91, 105, and 106 is a relative term which renders the claims indefinite. The term "about" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Attention is directed to MPEP 2173.05(b)A, which states in part:

In determining the range encompassed by the term "about", one must consider the context of the term as it is used in the specification and claims of the application. *Ortho-McNeil Pharm., Inc. v. Caraco Pharm. Labs., Ltd.*, 476 F.3d 1321, 1326, 81 USPQ2d 1427, 1432 (Fed. Cir. 2007). In *W. L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983), the court held that a limitation defining the stretch rate of a plastic as "exceeding about 10% per second" is definite because infringement could clearly be assessed through the use of a stopwatch. However, the court held that claims reciting "at least about" were invalid for indefiniteness where there was close prior art

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and there was nothing in the specification, prosecution history, or the prior art to provide any indication as to what range of specific activity is covered by the term "about."

*Amgen, Inc. v. Chugai Pharmaceutical Co.*, 927 F.2d 1200, 18 USPQ2d 1016 (Fed. Cir. 1991).

"The use of the word 'about,' avoids a strict numerical boundary to the specified parameter."

*Ortho-McNeil Pharmaceutical, Inc. v. Caraco Pharmaceutical Laboratories, Ltd.*, 476 F.3d

1321, 1326 (Fed. Cir. 2007) (quoting *Pall Corp. v. Micron Separations, Inc.*, 66 F.3d 1211, 1217

(Fed. Cir. 1995)); *see also In re Harris*, 409 F.3d 1339, 1343 (Fed. Cir. 2005) ("[U]se of the term

'about' shows that the applicants did not intend to limit the claimed ranges to their exact endpoints.").

However, "the word 'about' does not have a universal meaning in patent claims[;]" rather, "the meaning depends on the technological facts of the particular case." *Pall Corp.*, 66 F.3d at 1217; *see also Eiselstein v. Frank*, 52 F.3d 1035, 1040 (Fed. Cir. 1995) ("The meaning of the word 'about' is dependent on the facts of a case, the nature of the invention, and the knowledge imparted by the totality of the... disclosure to those skilled in the art."). Thus, in evaluating the scope of the "about," it is appropriate to look how the Specification and other claims use the term, as well as considering the effects of varying the parameter described by the term. *Pall Corp.*, 66 F.3d at 1217.

9. Claims 10, 50, 64, 71, 79, and 89 are indefinite with respect to what constitutes the meets and bounds of "change" as it relates to a "change" in a "fluorescent property."

Acknowledgement is made of dependent claims 17, 54, 68, 76, and 97 providing a non-limiting group of alternative properties. However, the remaining dependent claims are not so limited.

Accordingly, it is not readily apparent as to just what "fluorescent properties" are being

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encompassed by not only the independent claims and those of the dependent claims, keeping in mind the requirements of 35 USC 112, fourth paragraph.

10. Claims 108-111 are indefinite with respect to what constitutes the metes and bounds of “a native polymerase.” Said claims are also indefinite with respect to how the polymerase is to be construed as “native” when it has undergone mutation.

11. Claims 108-111 are indefinite with respect to what constitutes the metes and bounds of “involved.”

12. Claims 108-111 are indefinite with respect to what constitutes the metes and bounds of “cysteine residue replacement” and “cysteine residue replacements.”

### ***Claim Rejections - 35 USC § 102***

13. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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15. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

16. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

17. Claims 10, 16-18, 50, 51, 53-55, 64-69, 71, 72, 74, 76, 77, 79-82, 84-87, 89-92, 95-98, 100, 102-106, and 108-111 rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over US Patent 7,033,764 B2 (Korlach et al.).

18. The instant application claims benefit of priority to provisional application 60/216,594, foiled 07 July 2000. Korlach et al., claims benefit of priority to Provisional Application 60/134,827, filed 19 May 1999. Accordingly, Korlach et al., qualifies as 102(e)-type art.

19. Korlach et al., disclose methods and related reagents for conducting sequencing of nucleic acids. As set forth in column 26, first paragraph, the reaction may be conducted with fluorescent resonant energy transfer where the polymerase has one member of a fluorescent label



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pair and the nucleotide comprises the second fluorescent label. As disclosed therein, one label acts as a donor and the other acts as an acceptor of the donated fluorescent energy transfer.

20. Korlach et al., column 14, last paragraph, teach that the label may be attached to a beta- or gamma-phosphate. The placement of a label on such a phosphate meets the limitation that the label would be removed by action of the polymerase on the dNTP (formation of a pyrophosphate).

21. Korlach et al., column 9, first full paragraph, provides a non-exhaustive listing of polymerases and transcriptases that can be included. Specifically identified are DNA polymerases, RNA polymerases, and a variety of reverse transcriptases, including HIV-1 reverse transcriptase. (See also claim 3 and column 10, third paragraph). Such a showing is deemed to meet a limitation of claims 51, 65, 72, and 92 as it relates to the inclusion of a reverse transcriptase; and also meets a limitation of claims 53, 67, 74, and 95 as it relates to the composition comprising HIV-1 reverse transcriptase.

22. Korlach et al., column 4, penultimate paragraph, teach that the use of a polymerase that lacks exonuclease activity (applicant's "the polymerizing agent lacks the ability to remove previously incorporated nucleotide."). Such a showing meets a limitation of claims 100 and 102-104.

23. Korlach et al., column 12, penultimate paragraph, teach that nucleotide incorporation can be determined by detecting a specific frequency of fluorescent label that is associated with a particular nucleotide, and that also intensity and duration of signal can be used as criteria for evaluation. Such disclosure is deemed to meet a limitation of claims 17, 54, 68, 74, 86, and 97.

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24. Claims 108-111 depend from each of the independent claims and seek to further define the polymerase in terms of a product-by-process limitation. With respect to product-by-process claims, it is "well settled that the presence of process limitations in product claims, which product does not otherwise patentably distinguish over the prior art, cannot impart patentability to that product." *SmithKline Beecham Corp. v. Apotex Corp.*, 439 F.3d 1312, 1318 (Fed. Cir. 2006) (quoting *In re Stephens*, 345 F.2d 1020, 1023 (CCPA 1965). As stated in *In re Thorpe*, 777 F.2d 695,697 (Fed. Cir. 1985) (citations omitted):

[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in a product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.

25. The examiner takes notice that a compound and its properties are inseparable. While Korlach et al., has not been found to definite the polymerase in terms of specific residues, it is noted that the polymerases disclosed by Korlach et al., are fairly encompassed by the claimed composition. Further, the properties disclosed by Korlach et al., e.g., use in FRET-based nucleic acid sequencing, are the same. Accordingly, and in the absence of convincing evidence to the contrary, the modified polymerases disclosed and used by Korlach et al., are deemed to anticipate the composition as claimed in dependent claims 108-111. In the event that Korlach et al., is found to not anticipate this limitation, such a composition would still have been obvious to one of ordinary skill in the art at the time the invention was made as there are but a finite number of suitable amino acids to which one could attach the label and still retain functionality of both the polymerase and FRET.

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26. For the above reasons, and in the absence of convincing evidence to the contrary, claims 10, 16-18, 50, 51, 53-55, 64-69, 71, 72, 74, 76, 77, 79-82, 84-87, 89-92, 95-98, 100, 102-106, and 108-111 rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over US Patent 7,033,764 B2 (Korlach et al.).

### ***Conclusion***

27. Objections and/or rejections which appeared in the prior Office action and which have not been repeated hereinabove have been withdrawn.

28. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradley L. Sisson whose telephone number is (571)272-0751. The examiner can normally be reached on 6:30 a.m. to 5 p.m., Monday through Thursday.

29. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave T. Nguyen can be reached on (571) 272-0731. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

30. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would

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like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Bradley L. Sisson/

Primary Examiner, Art Unit 1634